

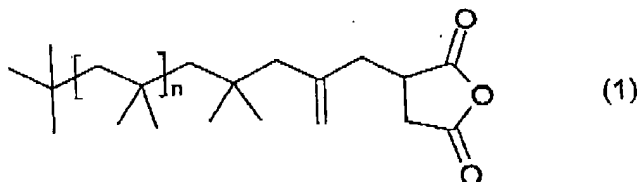
Attorney's Docket: 2000DE443
Serial No.: 10/003.656
Response to Final Action mailed 07/01/2004

REMARKS

The Office Action mailed July 1, 2004 has been carefully considered together with each of the references cited therein. The amendments and remarks presented herein are believed to be fully responsive to the Office Action. Reconsideration of the present Application in view of the following remarks is respectfully requested.

Applicant has amended the Application to attend to housekeeping matters and to more clearly describe the invention. Claims 10, 20 and 21 were amended to replace the term "mono- and/or polyfunctional" alcohol with the term - mono-functional- - alcohol. Support for this amendment may be found in originally filed claims 10 and 20-21. It is not believed that any new matter was introduced by these amendments, and that no additional search is required by the office.

Applicant's invention relates to the discovery that new compositions of cosmetics and pharmaceuticals can be formulated with emulsifiers derived from alkenylsuccinic anhydride of formula (1) when the anhydride group is reacted with a mono-functional alcohol, wherein the tail of the alkenylsuccinic anhydride has more than 28 carbon atoms as designated in formula (1):

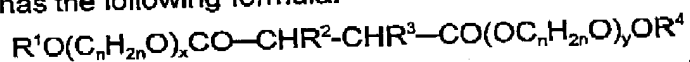


wherein n is equal to or greater than 4. The mono-functional alcohol, comprises alcohols which have an ether group and which is selected from the group consisting of a ethoxylated monoalcohol, a propoxylated monoalcohol, a fatty alcohol ethoxylate, methyl glycol, methyl triglycol, and mixtures thereof. Such mono-functional alcohols have at least one oxygen atom that is attached to two hydrocarbon moieties. Cosmetic formulations with and without fragrance prepared with the emulsifier based on the alkenylsuccinic acid or anhydride were found to provide stable emulsions, provided good skin compatibility, and good compatibility with customary cosmetic ingredients. Similarly, pharmaceutical formulations based

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on emulsifiers of the present invention had good compatibility with pharmaceutical ingredients and provided high stability.

Claims 3, 10, and 20-24 were again rejected under 35 USC § 103(a) as being unpatentable over Eierdanz et al. (5,650,158) in view of Carey et al. (XP-002950021) and in view of *The Handbook of Cosmetic Science and Technology*. This rejection is respectfully traversed. The examiner rejected claim 10 on the basis that US 5,650,158 to Eierdanz et al. ('158) would teach compounds similar to those described in claim 10 of the instant application, but without the polyisobutenyl group. The examiner relied on the Carey et al. reference to teach that the polyisobutenyl group would be advantageous and therefore, a combination of the '158 reference and the reference of Carey et al. would lead to the emulsifiers of claim 10 of the instant application. However, the examiner has failed to establish a prima facie case and has combined references where there is no motivation to make such a combination. The '158 reference is directed to a cosmetic preparation containing a composition, and as recite in the abstract and in claim 1 of the '158 patent, the composition has the following formula:



wherein R^1 is alkyl, alkenyl, mono- or dihydroxyalkyl or hydroxyalkenyl group **containing 6 to 22 carbons**, and one of R^2 or R^3 is hydrogen and the other is an alkyl or alkenyl containing 12-22 carbon atoms, where x and y are degree of alkoxylation and are 0 to 20 and 1 to 21, respectively, and R^4 is hydrogen or a group $R^1O(C_nH_{2n}O)_xCO-CHR^2-CHR^3-CO-$, or an alkyl, alkenyl, mono- or dihydroxyalkyl or hydroxyalkenyl group **containing 6 to 22 carbons**. The '158 reference is silent on the tail of the compound being a hydrophobic polyisobutenyl group. To introduce to the '158 reference a hydrophobic polyisobutenyl group would result in an increase the number of carbon atoms in the tail to at least 28. **The hydrophobic tail of the succinic anhydride of the '158 reference is limited to a maximum of 22 carbon atoms** (See '158, claim 1 and column 2, lines 21-22). **Applicant's claim 10 recites a minimum of 28 carbon atoms in the tail as shown by the formula (1) for the polyisobutylene substituent, wherein n is equal to or greater than 4.** Therefore, the '158 reference teaches away from the instant invention by the limitation of the

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number of carbon atoms to less than 22 carbons in the hydrophobic tail which is attached to the succinicanhydride portion of the succinicanhydride molecule.

The Carey et al. reference is a general handbook reference on the chemistry of alkenyl succinic anhydride emulsifiers and discloses that such compounds have a tail and headgroups. More specifically, the Carey et al. reference relates to water-in-oil emulsions, or invert emulsions, and discloses that alkenyl succinicanhydride based emulsifiers are characterized as having a tail group and headgroups, and that the choice of the headgroup and tail can lead to a wide variety of properties which include stability, texture and stickiness. With reference to personal care, the reference points out that invert emulsions have not found wide spread use, because these emulsions have a poor feel:

"In general, invert emulsions have the potential for providing extremely rich textured skin and hair care products, but they also have a tendency to be oily and sticky."

On page 5, Carey et al. states that a 100% waxy straight chain tail improves the texture, while reducing stability, and a highly branched tail, such as a polyisobutylene will tend to be tacky. The reference concludes with the teaching that **a balance of short, waxy chains and longer branched chains is required to achieve the appropriate texture.**

Now, to the question of whether one skilled in the art would combine the '158 reference with the polyisobutylene tail of the Carey et al. reference to arrive at Applicant's invention. The compounds of claim 10 of the instant application are esters of succinicanhydride of formula (1) and the monofunctional alcohol. These compounds comprise two functional parts:

a **hydrophobic** part (a polyisobutenyl tail with at least 28 carbon atoms – according to claim 10 (formula(1) of the instant application wherein **n is equal or greater than 4**), and
a **hydrophilic** part (the ester groups (headgroup) comprising mono-functional alcohols having an ether functionality and the groups attached to the ester group and resulting from the alcohol used to prepare the ester).

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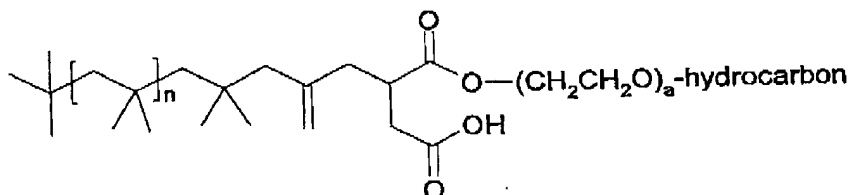
The examiner correctly states that the '158 reference is silent on the hydrophobic polyisobutenyl group. To introduce the hydrophobic polyisobutenyl group of the Carey et al. reference would require an increase the number of carbon atoms in the tail to at least 28. However, **the hydrophobic tail of the succinic anhydride of the '158 reference is limited to a maximum of 22 carbon atoms** (See '158, claim 1 and column 2, lines 21-22). Thus, the '158 reference teaches away from the instant invention by the limitation of the number of carbon atoms to less than 22 carbons in the hydrophobic tail which is attached to the succinic anhydride portion of the molecule. Therefore, no one skilled in the art would arrive at Applicant's claimed invention by the simple combination of the polyisobutylene tail from the Carey et al. reference and the alkenylsuccinic anhydride based material of the '158 patent.

Regarding Applicant's headgroup:

According to claim 10, the hydrophilic part of Applicant's molecule, the starting materials are the succinic anhydride of formula(1) and the monofunctional alcohol is an alcohol which also contains at least one ether group. The alcohols disclosed in the '158 reference do not have an ether functionality. With reference to the '158 reference, when R¹OH is a fatty alcohol such as stearyl, or behenyl alcohol, there is no ether functionality. When R¹ is mono- or dihydroxyalkyl or hydroxyalkenyl, these are hydrocarbon groups wherein one or two hydrogen atoms are replaced by one or two alcohol hydroxyl functions, but which do not comprise any ether functions. Examples of the corresponding R¹OH alcohols include alkane diols and alkane triols which do not comprise ether functions. Thus, the compounds of claim 10 of the instant application are compounds comprising one ester group -COO- and one carboxylic group -COOH (monoester) or two ester groups (diester). Attached to the ester groups are alkyleneoxy groups and attached to these alkyleneoxy groups are hydrocarbon groups. The alkyleneoxy and the hydrocarbon groups originate from the alcohol used to prepare the ester.

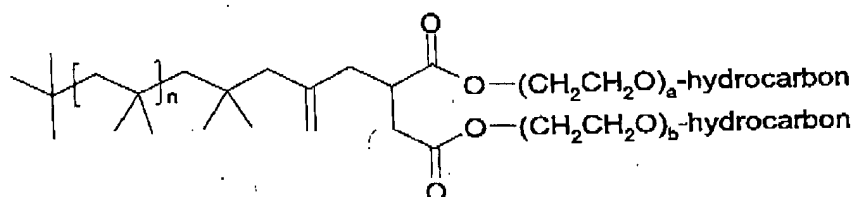
The compounds according to claim 10 of the instant application are illustrated hereinbelow for the case wherein the alkyleneoxy is ethyleneoxy -CH₂CH₂O-:

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monoester

a not= 0

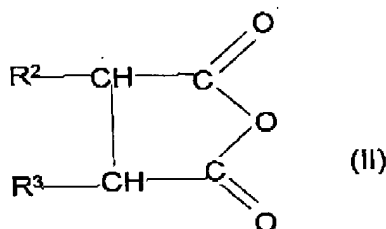


diester

a and b not= 0

A further example for the compounds according to the instant invention can be found in Applicant's preparation example 4 at paragraph [0070] of Applicant's Specification wherein only one of the carboxylic functions originating from the succinicanhydride is esterified.

Applicant's composition results from the reaction of the alkenylsuccinic anhydride of formula (I) with Applicant's mono-functional alcohol having the ether functionality and the result is different from the composition of the '158 reference. According to the '158 reference (column 2, lines 1-20), a succinic acid derivative is produced from the starting point of a succinicanhydride of the general formula (II):

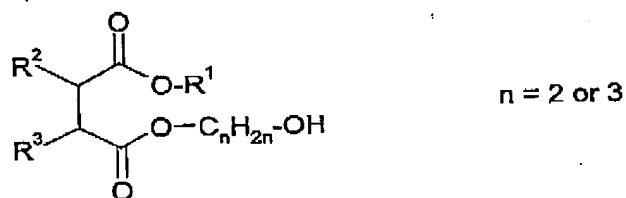


wherein R² and R³ is hydrogen and the other is an alkenyl group containing 12 to 22 carbon atoms. Succinicanhydride of formula (II) is reacted with an alcohol R¹-OH to form a monoester, and the monoester is then alkoxyated with ethylene oxide or propylene oxide. The definition for R¹ is given in the '158 reference at column 1,

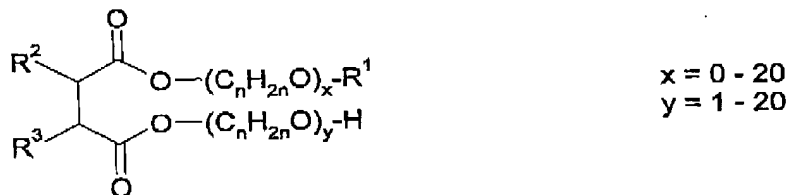
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lines 45-47. The '158 reference discloses that the alkoxyated monoester may be hydrogenated to saturate double bonds present in the molecule.

The end product of the '158 patent is a broad mixture of materials in contrast to Applicant's pure product which is free of potentially toxic by-products such as would have been produced in the method disclosed in the '158 reference. When the alkoxylation of the monoester of the '158 patent is carried out with ethylene oxide or propylene oxide, the carboxylic function of the monoester that is not esterified will react (see column 2, lines 35-38 of the '158 reference). Therefore, if only one molecule of monoester and one molecule of alkylene oxide are used in the reaction the following compounds will result:



When more than one molecule (x+y molecules) of alkylene oxide (ethylene oxide or propylene oxide) are used in the reaction the compounds of the following formula are produced (in column 2, lines 43-53 of the '158 reference these compounds are also referred to as "the main component of the reaction mixture"):



Because y has to be at least 1, the compounds formed according to the teaching of the '158 reference will always have a different hydrophilic part than the compounds according to claim 10 of the instant application. The compounds of the '158 reference will always have at least one additional group -

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$C_nH_{2n}O-$. Furthermore, the reaction products of '158 are not ethers which are based on the succinicanhydride and a selected mono-alcohol, the product of the '158 reference is **always complex mixtures of different compounds**. In accordance with this statement '158 teaches that "monoester ethoxylates corresponding to formula I, in which $R^4 = H$, are the main component of the reaction mixture" (see column 2, lines 51 - 53). The reason for the fact that the reaction products of '158 always are complex mixtures is related to the preparation procedure used by '158 and in particular is related to the alkoxylation step. The alkoxylation step leads to compounds with different degrees of alkoxylation and to "dimers" but also to other undesirable by-products. In the '158 patent, the dimers are disclosed in column 2, lines 43 - 50 wherein when R^4 is $R^1O(C_nH_{2n}O)_xCO-CHR^2-CHR^3-CO-$.

If in the '158 reference, " R^4 " of formula (I) in column 1, line 45 is replaced with named residue a "symmetrical" compound will result. This compound comprises two $-CHR^2-CHR^3-$ groups which means that it was generated from two compounds of the formula (II) of column 2, lines 5 - 10 of the '158 reference and therefore is a so-called dimer. In contrast thereto, the esters of the instant application are produced solely by an esterification step avoiding the production of any dimers, and no further alkoxylation step is performed. In the instant invention no alkoxylation step is required because the alcohols used for the esterification reaction are already alkoxyated (see claim 10 of the instant application: "ethoxylated" monoalcohol, "propoxylated" monoalcohol etc.). Accordingly in the instant invention, pure compounds may be obtained, when pure mono-alcohols are used for the esterification. Furthermore, no dimers can result because monoalcohols are used in the esterification reaction. Furthermore, the alkoxylation step of the '158 reference results in the formation of undesirable toxic by-products such as dioxane, which Applicant's process avoids. Thus, the product of Applicant's process is different from the product of the '158 reference. The starting materials are different and the resulting product is different and, in fact, superior by being more pure and free of undesirable and potentially toxic by-products. Therefore there the '158 reference does not teach or suggest the formation of Applicant's ester of succinicanhydride,

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and the specific limitations of the number of carbon atoms in either R² or R³ of the '158 patent teach away from replacing either R² or R³ with a polyisobutylene tail having at least 28 carbon atoms.

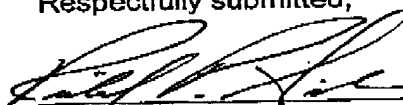
In *re Thorpe*, 777 F.2d 695, 698, 277 USPQ 964, 966 (Fed. Cir. 1985), relates to a case where the PTO properly used the applicant's statement of chemical fact that the properties of the product claimed by reference to the applicant's new process was about equal to a prior art product produced another process. In *Thorpe*, the end product of the applicant's product-by-process claim and the prior art product were identical, the only difference being that the process of *Thorpe* produced one of the components of the product in-situ. In *re Thorpe* is not applicable to the instant case wherein the prior art product of the '158 reference is different from the instant invention, and the '158 reference teaches away from the instant invention. Therefore any rejection based on In *re Thorpe* is improper and should be withdrawn.

Therefore, the rejection of Claims 3, 10, and 20-24 under 35 USC § 103(a) as being unpatentable over *Eierdanz et al.* (5,650,158) In view of *Carey et al.* (XP-002950021) and in view of *The Handbook of Cosmetic Science and Technology*, should be withdrawn for the reason that the '158 reference teaches away from the instant invention by disclosing a compound with an alkenyl group of at most 22 carbon atoms does not fairly teach or suggest the compound claimed by the applicant which has a hydrophobic part having at least 28 carbons, and that one skilled in the cosmetic and pharmaceutical art would not be motivated to modify the compound of the '158 reference with polyisobutylene the *Carey et al.* reference to obtain the instant invention for the reasons given hereinabove, and that any determination that applicant's compound was obvious-to-try is based on improper hindsight. The *Handbook* reference appears to have been relied on for the inclusion of a fragrance as a material which is generally combined with cosmetic emulsifiers, but the examiner has failed to produce showing that Applicant's emulsifier is obvious from a combination of the '158 and the *Carey et al.* references and that anyone skilled in the art would be motivated to combine the references to obtain applicant's invention.

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It is respectfully submitted that, in view of the above remarks, the objection to the Specification, the rejections under 35 U.S.C. 103(a), should be withdrawn and that this application is in a condition for an allowance of all pending claims. Accordingly, favorable reconsideration and an allowance of all pending claims are courteously solicited.

Respectfully submitted,



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